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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,422	05/22/2000	Michel Schneider	1889-33	2399

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KRAMER LEVIN NAFTALIS & FRANKEL LLP  
INTELLECTUAL PROPERTY DEPARTMENT  
1177 AVENUE OF THE AMERICAS  
NEW YORK, NY 10036

EXAMINER
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KOHARSKI, CHRISTOPHER

ART UNIT	PAPER NUMBER
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3763

NOTIFICATION DATE	DELIVERY MODE
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08/13/2007

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

klpatent@kramerlevin.com

## Office Action Summary

Application No.

09/576,422

Applicant(s)

SCHNEIDER ET AL.

Examiner

Christopher D. Koharski

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 22-34 and 39-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9, 22-34, 39-43 and 45 is/are rejected.
- 7) ☒ Claim(s) 7, 8 and 44 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

Examiner acknowledges the reply filed 9/06/2006 in which no claims were amended and new claims 43-45 were added. Currently, claims 1-9, 22-34 and 39-45 are pending for examination in this application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 9, 22-27, 39, 43 and 45 are rejected under 35 U.S.C. 103(a) as being obvious over Pokras U.S. Patent Number 5,647,851 in view of Schneider et al U.S. Patent Number 5,686,060.

Pokras discloses a method of administering by injection a suspension by means of an injected system (16) comprising a syringe (14) containing the suspension and a power driven piston (48) for injecting the suspension into a patient comprising by

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subjecting the suspension in the syringe to a alternated rotation or rocking motion, and wherein the motion is provided by outside means (16) by a syringe supporting bracket (16) with an attached motor driven unit (32); and wherein the motion is alternated, applied along or around the syringe longitudinal or transverse axis and the syringe is subject to continuous or intermittent rotation at 0.5 to 200 rpm (col. 8 lines 41-55). Furthermore, Pokras teaches that the motion is carried out stepwise (col. 9 lines 28-31), and the suspension is a contrast agent for ultrasonic imaging of patients.

Pokras fails to explicitly disclose that the method is for suspension of microparticles homogeneously distributed in an aqueous solution, nor that the type of gas or composition of the surfactant and polymers.

Schneider et al discloses a similar method in which is disclosed a method for suspension of microparticles (col. 5 line 23), and that the gas is a halogenated gas  $CF_4$ , the gas is nitrogen (col. 6 line 60), the surfactant is a saturated phospholipids in a lamellar or laminar flow (col. 4 line 63). It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Pokras by incorporating the compositions as described by Schneider et al in order to create more stable microbubbles (col. 3 line 39).

Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pokras and Schneider et al and further in view of Unger et al U.S. Patent Number 6,028,066.

Pokras in view of Schneider et al disclose the method as described above in reference to claim 24 but fail to explicitly disclose the fatty acid residue and the composition of the membrane.

Unger et al discloses a similar method in which one of the phospholipids is a diacylphosphatidyl, the polymer of the membrane is selected from polyglycolic acid, the material envelope of the microballoon is made from albumin, bounded by saturated triglycerides.

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Pokras and Schneider et al by incorporating the compositions as taught by Unger et al in order to increase the signal received from micobubbles and decrease background tissue signals.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pokras in view of Schneider et al and Unger ('066) and further in view of Unger U.S. Patent Number 5,334,381. The above-mentioned references disclose the method as described above in reference to claim 32, but fail to disclose that the liposomes are filled with an iodinated compound.

Unger ('381) discloses a similar method in which the liposomes are filled with an iodinated compound (col. 8 line 21). It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Pokras, Schneider et al and Unger ('066) by incorporating the compositions as taught by Unger ('381) in order to better detect tumors in the liver (col. 8 line 21).

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pokras in view of Schneider et al and Unger ('066) and Unger ('381) and further in view of Minchey et al U.S. Patent Number 5,415,867. The above-mentioned references disclose the method as described above in reference to claim 33, but fail to disclose that the iodine over lipid ratio is 3 or more.

Minchey discloses a similar method in which the iodine over lipid ratio is 3 or more (see table 1). It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Pokras, Schneider et al and Unger ('066), and '381) by incorporating the compositions as taught by Minchey in order for better contrast agent detection.

Claims 40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pokras in view of Schneider et al and further in view of Unger ('381). Pokras in view of Schneider, discloses the method as described above in reference to claims 39 and 41, but fails to explicitly disclose that the organ imaged is the liver.

Unger ('381) discloses a similar method in which the organ imaged is the liver (col. 14 line 23). It would have been obvious to one having ordinary skill in the art at the time of invention by the applicant to modify the device of Pokras by incorporating the step of imaging the liver as described by Unger ('381).

***Allowable Subject Matter***

Claims 7–8 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

Applicant's arguments filed 9/09/2006 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Pokras (5,647,851) does not disclose a rotation or rocking motion and is not capable of suspending micro-bubbles.

Examiner has fully considered Applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the Pokras reference does disclose a rotational or rocking motion as depicted in Figures 10-11, and Pokras discloses that the needle (and thus syringe barrel) moves in an orbital or axially reciprocating path (i.e. rocking) (col 10, In 40-50). The declaration discloses segregation of micro-bubbles is not possible with Pokras, (only micro-particles are claimed) Examiner asserts the Pokras reference is capable of keeping micro-particles separated because it operates in the same manner as the invention currently claimed and variations of the motor size and weight will change the vibrational characteristics which was not addressed in the declaration.

Theefore prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date:

7/27/2007



Christopher D. Koharski  
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